

## **DETAILED ACTION**

### ***Note to Applicant***

This application contains two claims numbered 38, one of which is dependent on claim 37 and one of which is an independent claim. For purposes of this election/restriction requirement, the claim 38 that is dependent on claim 37 will be referred to as claim 38A. The claim 38 that is independent will be referred to as 38B.

### ***Election/Restrictions***

#### **Restriction**

Restriction to one of the following inventions is required under 35 U.S.C. 121:

- I. Claims 1-31, drawn to a bone anchor, classified in class 606, subclass 73.
- II. Claims 32-35, drawn to a spinal stabilization system, classified in class 606, subclass 61.
- III. Claims 36-43, drawn to methods for spinal fixation, classified in class 606, subclass 60.

Inventions I and II are related as combination and subcombination. Inventions in this relationship are distinct if it can be shown that (1) the combination as claimed does not require the particulars of the subcombination as claimed for patentability, and (2) that the subcombination has utility by itself or in other combinations (MPEP § 806.05(c)). In the instant case, the combination as claimed does not require the particulars of the subcombination as claimed because the claimed combination

(Invention II) does not require the claimed characteristics of the various portions (engagement, head, and flexible) of the subcombination (Invention I). The subcombination has separate utility such as mending a fracture.

The examiner has required restriction between combination and subcombination inventions. Where applicant elects a subcombination, and claims thereto are subsequently found allowable, any claim(s) depending from or otherwise requiring all the limitations of the allowable subcombination will be examined for patentability in accordance with 37 CFR 1.104. See MPEP § 821.04(a). Applicant is advised that if any claim presented in a continuation or divisional application is anticipated by, or includes all the limitations of, a claim that is allowable in the present application, such claim may be subject to provisional statutory and/or nonstatutory double patenting rejections over the claims of the instant application.

Inventions II and III are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product. See MPEP § 806.05(h). In the instant case, the process can be practiced with another materially different product.

Inventions I and III are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different

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process of using that product. See MPEP § 806.05(h). In the instant case, the process can be practiced with another materially different product.

### Election

This application contains claims directed to the following patentably distinct species:

- If Applicant chooses Invention I from above, an election is required from the following species:
  - The bone anchor illustrated in Figure 1. If Applicant elects this species, Applicant must further choose one from each of the following categories of subspecies:
    - A flexible portion:
      - Figure 1
      - Figure 2A
      - Figure 2B
    - A head portion:
      - Figure 1
      - Figure 4A
      - Figure 4B
      - Figure 4C
      - Figure 6A
      - Figure 6B
  - The bone anchor illustrated in Figure 7. If Applicant elects this species, Applicant must further choose from the following subspecies:
    - A flexible portion:
      - Figure 7
      - Figure 8A
      - Figure 8B
  - The bone anchor illustrated in Figure 10. If Applicant elects this species, Applicant must further choose from the following subspecies:
    - A flexible portion
      - Figure 10
      - Figure 11
  - The bone anchor illustrated in Figure 13.

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- If Applicant chooses Invention II from above, an election is required from the following species:
  - A bone anchor.
    - Figure 1
    - Figure 7
    - Figure 10
    - Figure 13
- If Applicant chooses Invention III from above, an election is required from the following species:
  - A method for stabilization comprising permitting deflection of the bone anchor as shown in Claims 36-38A.
  - A method for stabilization comprising bone anchors configured to produce a center of rotation as shown in Claim 38B.
  - A method for stabilization comprising introducing a device into the intervertebral space as shown in Claims 41-43.
  - An improved method for the correction of scoliosis as shown in Claim 39.
  - An improved method for the correction of spondylolisthesis as shown in Claim 40.

The species are independent or distinct because claims to the different species recite the mutually exclusive characteristics of such species. In addition, these species are not obvious variants of each other based on the current record.

Applicant is required under 35 U.S.C. 121 to elect a single disclosed species for prosecution on the merits to which the claims shall be restricted if no generic claim is finally held to be allowable. Currently, no claims are generic.

There is an examination and search burden for these patentably distinct species due to their mutually exclusive characteristics. The species require a different field of search (e.g., searching different classes/subclasses or electronic resources, or employing different search queries); and/or the prior art applicable to one species would

not likely be applicable to another species; and/or the species are likely to raise different non-prior art issues under 35 U.S.C. 101 and/or 35 U.S.C. 112, first paragraph.

Applicant is advised that the reply to this requirement to be complete must include (i) an election of a species to be examined even though the requirement may be traversed (37 CFR 1.143) and (ii) identification of the claims encompassing the elected species, including any claims subsequently added. An argument that a claim is allowable or that all claims are generic is considered nonresponsive unless accompanied by an election.

The election of the species may be made with or without traverse. To preserve a right to petition, the election must be made with traverse. If the reply does not distinctly and specifically point out supposed errors in the election of species requirement, the election shall be treated as an election without traverse. Traversal must be presented at the time of election in order to be considered timely. Failure to timely traverse the requirement will result in the loss of right to petition under 37 CFR 1.144. If claims are added after the election, applicant must indicate which of these claims are readable on the elected species.

Should applicant traverse on the ground that the species are not patentably distinct, applicant should submit evidence or identify such evidence now of record showing the species to be obvious variants or clearly admit on the record that this is the case. In either instance, if the examiner finds one of the species unpatentable over the prior art, the evidence or admission may be used in a rejection under 35 U.S.C. 103(a) of the other species.

Upon the allowance of a generic claim, applicant will be entitled to consideration of claims to additional species which depend from or otherwise require all the limitations of an allowable generic claim as provided by 37 CFR 1.141.

### ***Conclusion***

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Julianna N. Harvey whose telephone number is (571)270-3815. The examiner can normally be reached on Mon. - Thurs., 7:30 a.m. - 5:00 p.m.; Fri., 8:00 a.m. - 4:30 p.m. EST.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Gary Jackson can be reached on 571-272-4697. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

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JNH

/J.N.H./

12/19/07

/Gary Jackson/

Supervisory Patent Examiner

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